wherein said composition is formulated for administration for bioavailability to produce a serum or target tissue concentration of alpha-acid and/or beta-acid components in a range of about 0.005 to 10,000 ng/mL; and

wherein said composition is formulated into a form selected from the group consisting of capsule, tablet, injectable solution, injectable suspension, spray solution, spray suspension, lotion, and food.

9. (Twice Amended) The composition of Claim 1, wherein the pharmaceutical grade CO_2 extract of hops comprises 30 to 60 percent alpha acids and 15 to 45 percent beta acids.

REMARKS

Claims 1 and 9 have been amended and Claims 2 and 10 have been cancelled without prejudice. As a result, Claims 1, 3-4, 6-9, 12-13, and 15-17 remain pending in the present application. Support for the amendments is found in the existing claims and specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

Applicant would initially like to thank Examiner Meller for the courteous interview extended to the Applicant's representatives, Daniel Altman and Connie Tong, on July 30, 2002. Applicant has amended the claims along the lines discussed during the interview. On the basis of the interview and in response to the Office Action mailed May 23, 2002, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

The specific changes to the amended claims are shown on a separate set of pages attached hereto and entitled VERSION WITH MARKINGS TO SHOW CHANGES MADE, which follows the signature page of this Amendment. On this set of pages, the insertions are underlined while **[the deletions are bolded and bracketed]**.

Amendment to Claim 1

Claim 1 has been amended to recite "a composition for inhibiting inducible COX-2 activity, comprising a pharmaceutical grade CO_2 extract of hops and a pharmaceutically

acceptable carrier; wherein said composition is formulated for administration for bioavailability to produce a serum or target tissue concentration of alpha-acid and/or beta-acid components in a range of about 0.005 to 10,000 ng/mL; and wherein said composition is formulated into a form selected from the group consisting of capsule, tablet, injectable solution, injectable suspension, spray solution, spray suspension, lotion, and food." Support for the amendment can be found on page 14, lines 11-13, and page 15, lines 15-26 of the Specification. Accordingly, no new matter is added herewith.

Rejection under 35 U.S.C. § 112

The Examiner rejected Claims 1-4, 6-10, 12, 13, and 15-17 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. In particular, the Examiner believes the term "consisting essentially of" is vague. Claim 1 has been amended, as explained above, and does not recite "consisting essentially of". All other pending claims depend from Claim 1. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 102

The Examiner rejected Claims 1, 3, 4, and 6 under 35 U.S.C. § 102(b) as being anticipated by Haas (U.S. Patent No. 3,932,603).

According to M.P.E.P. 2131, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Haas discloses an oral preparation for inhibiting dental caries in the mouth. According to the Examiner, Haas teaches a composition containing hop extract which contains lupulone and humulone and sweeteners. As stated in column 1, lines 53-63, Haas discloses an oral preparation for inhibition of dental caries. "The preparations can take the form of toothpastes, tooth powders and mouthwashes, or the like, but since it is highly desirable to have the active ingredient present in the mouth for extended periods, the preparations may also be in the form of chewing gum or of a lozenge or drop which can be slowly dissolved in the mouth."

Claim 1 has been amended to recite, *inter alia*, "wherein said composition is formulated for administration for bioavailability to produce a serum or target tissue concentration of alpha-

acid and/or beta-acid components in a range of about 0.005 to 10,000 ng/mL; and wherein said composition is formulated into a form selected from the group consisting of capsule, tablet, injectable solution, injectable suspension, spray solution, spray suspension, lotion, and food."

Since Haas discloses the forms of the preparations to be in contact with the surface of the mouth, such as toothpastes, tooth powders, mouthwashes, chewing gums, lozenges, and drops, Claim 1 is not anticipated by Haas. In column 1, lines 40-49 of Haas, the problem to be solved is "finding a means whereby the effective substance may be permitted to act in the mouth." Haas does not disclose that formulations can be administered in areas other than the surface of the mouth. Claim 1 recites "wherein said composition is formulated into a form selected from the group consisting of capsule, tablet, injectable solution, injectable suspension, spray solution, spray suspension, lotion, and food", which are not forms suitable for the purposes concerned in Haas and, therefore, neither disclosed nor suggested by Haas. As such, Claim 1 is not anticipated by Haas.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 102(b).

Rejection under 35 U.S.C. § 103

The Examiner rejected Claims 1-4, 6-10, 12, 13, and 15-17 under 35 U.S.C. § 103(a) as being unpatentable over Haas (U.S. Patent No. 3,932,603) when taken with Verluys (U.S. Patent No. 4,401,684) and Todd, Jr. (U.S. Patent No. 5,073,396).

According to M.P.E.P. 2143.03, "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art."

As stated above, Haas discloses an oral preparation for inhibiting dental caries in the mouth. As stated in column 1, lines 53-63, "The preparations can take the form of toothpastes, tooth powders and mouthwashes, or the like, but since it is highly desirable to have the active ingredient present in the mouth for extended periods, the preparations may also be in the form of chewing gum or of a lozenge or drop which can be slowly dissolved in the mouth."

According to the Examiner, Verluys teaches that vitamin C is used as an antioxidant to prevent the deterioration of hops.

According to the Examiner, Todd, Jr. teaches that hop in beer is routinely CO_2 extracted.

Amended Claim 1 is patentable even in light of Haas taken with Versluys (U.S. Patent No. 4,401,684) and Todd, Jr. (U.S. Patent No. 5,073,396). Amended Claim 1 recites, *inter alia*, "wherein said composition is formulated for administration for bioavailability to produce a serum or target tissue concentration of alpha-acid and/or beta-acid components in a range of about 0.005 to 10,000 ng/mL; and wherein said composition is formulated into a form selected from the group consisting of capsule, tablet, injectable solution, injectable suspension, spray solution, spray suspension, lotion, and food." As discussed above, neither Haas nor the secondary references provide a suggestion to provide a composition in one of the recited forms so as to achieve the recited target concentrations. In view of the foregoing, Applicant respectfully asserts that amended Claim 1 is allowable over the cited art.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

CONCLUSION

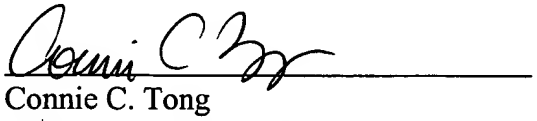
In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned in order to resolve such issue promptly.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 1, 2002

By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please cancel Claims 2 and 10 without prejudice.

Please amend Claims 1 and 9 as follows.

1. (Twice Amended) A composition **[consisting essentially of an alpha acid and a beta acid in a ratio that, when administered, is capable of inhibition of]** for inhibiting inducible COX-2 activity **[while having minimal effect on COX-1 activity]**, comprising a pharmaceutical grade CO_2 extract of hops and a pharmaceutically acceptable carrier;

wherein said composition is formulated for administration for bioavailability to produce a serum or target tissue concentration of alpha-acid and/or beta-acid components in a range of about 0.005 to 10,000 ng/mL; and

wherein said composition is formulated into a form selected from the group consisting of capsule, tablet, injectable solution, injectable suspension, spray solution, spray suspension, lotion, and food.

9. (Twice amended) **[A]** The composition **[for inhibition of inducible COX-2 activity and having minimal effect on COX-1 activity, said composition consisting essentially]** of Claim 1, wherein the pharmaceutical grade CO_2 extract of hops comprises 30 to 60 percent alpha acids and 15-45 percent beta acids.